IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Applicant Name, Address, and Contact:**

United Hearing Systems, Inc.
137 Norwich Road
Central Village, CT 06332
Tel: (860) 564-4130
Fax: (860) 564-5724
e-mail: rtcampagna@unitedhearing.com

Contact: Ralph Campagna

Date Prepared: March 7, 2005
Prepared by: Melissa Mazzoni

2. **Identification of the Device**

Proprietary Name:	TransEAR™ Bone Conduction Hearing Aid
Common Name:	Bone Conduction Hearing Aid
Classification:	Class II
CFR Section No:	874.3300
Product Code:	LXB

3. **Device Description:**

TransEAR™ is a bone conduction hearing aid. Unlike conventional air-conduction hearing aids, which depend on acoustic coupling through the air, TransEAR™ utilizes bone conduction technology to transmit sound vibrations through the bones of the skull to the cochlea.

TransEAR™ consists of a processor and a transducer (oscillator) connected via a wire cable. TransEAR's processor uses conventional digital hearing aid technology housed in a conventional behind-the-ear aid housing. The transducer is a mechanical oscillator housed in a conventional ear mold made of standard ear mold material. Each ear mold is custom made from an impression of the wearer's ear. A standard Zinc-Air hearing aid battery is utilized for power.

4. **Technological Characteristic of Substantially Equivalent Device(s):**

The TransEAR™ is substantially equivalent to the following devices:

- Starkey Model BC1 Bone Conduction CROS Hearing Aid
- Unitron® Bone Conduction Hearing Aid
- Second Ear® Bone Conduction Hearing Aid
- Branemark Bone Anchored Hearing Aid (BAHA)
- Various behind-the-ear air conduction hearing aids consisting of a digital sound processor and standard ear mold.

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Table 1: Comparison Table

Characteristic	TransEAR Bone Conduction Hearing Aid	Starkey BC1 Bone Conduction CROS Hearing Aid	Unitron Bone Conduction Hearing Aid	Second Ear Bone Conduction Hearing Aid	BAHA
510(k) No.	Pending	K923784	K884288	K953872	K021837 K042017
Design	Bone conduction hearing aid consisting of a processor and a transducer (oscillator) connected via a small wire cable. Vibrator is housed in a standard earmold.	Bone conduction hearing aid consisting of a processor and oscillator. Oscillator is connected via cord to microphone and amplifier housed in a headband.	Bone conduction hearing aid consisting of a processor and oscillator. Processor is connected to an oscillator by a cord attached to a headband.	Bone conduction hearing aid consisting of a processor and a oscillator connected via a small wire cable. The oscillator is held against the skull with a headband or strap.	Bone conduction hearing aid connected to a fixture pillar, which has been surgically placed in the bone behind the deaf ear.
Intended Use	To transmit sound through the skull bones for hearing.	Same	Same	Same	Same
Indications for Use	Indicated for persons with single sided deafness to provide the perception of sound from the deaf ear. The amplified signal is received into the deaf ear and transferred through the bones of the skull to the better cochlea.	Indicated for patients with conductive hearing losses and normal bone conduction hearing. Particularly useful for those with congenital atresia and require bone conduction amplification.	Indicated for moderate to severe conductive and mixed hearing losses that are complicated by congenital or accidental blockage of air conduction pathways.	Indicated for moderate to severe conductive hearing losses. Particularly useful for conductive losses compounded by congenital or secondary obstruction of auditory air conduction mechanisms.	The BAHA for single sided deafness (SSD) is indicated for patients who suffer from unilateral sensorineural deafness. Transmits sound from the deaf side through the bones in the skull to the normal functioning cochlea and is intended to improve speech recognition.
Materials	Biocompatible standard materials utilized in the hearing health industry.	Same	Same	Same	Same
Energy Source	Zinc-Air battery (675, 10A, or 13)	Same	Same	4.8 VDC Nickel-metal- hydride rechargeable battery	Same

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5. **Functional Testing**
   Functional testing of the TransEAR™ Bone Conduction Hearing Aid was conducted. Results of this testing indicate that the TransEAR™ is substantially equivalent to the predicate devices.

6. **Conclusion**
   It is the conclusion of United Hearing System, Inc. that the TransEAR™ Bone Conduction Hearing Aid is substantially equivalent to the predicated devices in terms of intended use, function, design, materials and performance. Additionally, United Hearing Systems concludes that there are no new concerns regarding safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 - 2005

United Hearing Systems, Inc.
c/o Ralph T. Campagna – CEO
137 Norwich Road
Central Village, CT 06332

Re: K050653
Trade/Device Name: TransEAR™ Bone Conduction Hearing Aid
Regulation Number: 21 CFR 874.3300
Regulation Name: Hearing aid
Regulatory Class: Class II
Product Code: LXB
Dated: June 23, 2005
Received: June 24, 2005

Dear Mr. Campagna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. INDICATIONS FOR USE

510(k) Number: K050653

Device Name: TransEAR™ Bone Conduction Hearing Aid

Indications for Use:

The TransEAR™ Bone Conduction Hearing Aid is indicated for persons with single sided deafness to provide the perception of sound from the deaf ear. The amplified signal is received into the deaf ear and transferred through the bones of the skull to the better cochlea.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over the Counter Use: _____
(Per 21CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050653